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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,736	07/13/2000	David Frederick Horrobin	P65773US0	4938

7590 05/12/2003

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EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/12/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,736

Applicant(s)

HORROBIN ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 21-39 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19, 21-39 and 42-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "fish oil" is not described or suggested by the specification, as originally filed.

Applicant's arguments filed April 1, 2003 have been considered but have not been found persuasive.

Applicants contend that the most obvious source of natural oils containing EFAs is fish oil. This argument has not been found persuasive since plants are also a source of natural EFAs. The specification fails to teach that fish oil is also a source of EFAs encompassed by the instant claims.

Claims 16-19, 21-39 and 42-47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haglund et al (Nutritional Research, Vol.13, pages 1351-1365, 1993).

Haglund et al disclose decrease in homocysteine levels after administration of a combination of fish oil, vitamin B6 and folic acid. The claimed methods are anticipated by Haglund et al. In addition, if there are any differences between the claimed method and the prior art method, the differences would appear to be minor in nature and the claimed method, which falls within the scope of the prior art method, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the instant invention was made.

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Claims 16-19, 21-39 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over den Heijer et al (Arterioscler. Thromb. Vasc. Biol. Vol. 18, 1998, pages 356-361) in combination with Horrobin (Prostaglandins Leukotr. Essential Fatty Acids, Vol. 53, 1995, pages 385-396) and Haglund et al (Nutritional Research, Vol. 13, pages 1351-1365, 1993).

den Heijer et al disclose that hyperhomocysteinemia is a risk factor for atherosclerosis and a reduction of homocysteine with vitamin B6, vitamin12 or folic acid alone or in combination.

Horrobin discloses the use of EFAs for the treatment of vascular disease.

A person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine B vitamins or folic acid disclosed by den Heijer et al with EFAs disclosed by Horrobin because Haglund et al disclose synergism when EFAs are administered in combination with B vitamins.

Horrobin also teaches that antioxidants are required because EFAs are readily oxidizable. Therefor, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to add well known antioxidants to a composition containing EFAs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev
May 9, 2003


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800